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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,064	02/13/2006	Kamalakar Talasila	GEN 3.3-015	4267

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EXAMINER	
CHANG, CELIA C	

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
02/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patpros@drreddys.com

Office Action Summary	Application No.	Applicant(s)	
	10/510,064	TALASILA ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Response filed by applicants dated Oct. 20, 2009 has been entered and considered carefully.

Claims 1-17 have been canceled.

The elected claim 37 wherein the antihistamine is fexofenadine hydrochloride form X with cellulose, mannitol, starch and croscarmellose, and the decongestant is a salt of pseudoephedrine and polyvinylacetate and povidone, thus, i.e. group I and claims 18-35 reading on the elected subject matter are pending. The remaining subject matter wherein antihistamine is selected from Fexofenadine (excluding hydrochloride in form X), Loratadine, Terfenadine, Cetrizine or a pharmaceutically acceptable salts thereof, or a decongestant selected from Pseudoephedrine, phenylephrine, phenylpropanolamine stayed withdrawn from consideration per 37 CFR 1.142(b).

No amendment to the claims was submitted.

2. The rejection of claims 37 and 18-36 reading on claim 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reason of record.

The specification lacks enablement as to how the *crystalline form X* can be prepare into a composition which can *maintain* the particular crystalline structure (claimed limitation) without the conventional recognized conversion to its thermodynamic form. Per ponderous of evidence in the prior art provided in the previous office action indicated that for a given polymorph, *absent of factual evidence* the compression process as disclosed in the specification does not *automatically* keep the specific crystalline form in the pharmaceutical composition. Absent of this composition, the bilayer composition with "form X" lacks enablement.

Applicants provided mere argument without factual evidence why in absence of guidance in *specific* carrier, *particular* steps which does *not dissolve* fexofenadine hydrochloride form X, therefore the claimed limitation of "fexofenadine hydrochloride form X" can be enabled. The office provided per ponderous of *factual* evidence in the prior art showing that using a solvent that dissolves the "crystal" would not produce a product that contains a particular crystalline form.

The gist of applicants' argument is in alleging that the US2005/0256163 reference is irrelevant. The particular section of the reference referred to in the previous office action is hereby recited:

> *Isopropyl-alcohol (150ml) and 32% HC1 solution (11.5g) were added to a reactor. The solution was cooled down to l 0°C under agitation. Fexofenadine base (50g) was added to a reactor. Agitation continued until full dissolution was obtained. The solution was cooled down (under agitation) to -12°C. Heptane (5ml) was added to the reactor and cloudiness appeared. After stirring the suspension for additional 2-16 hours, the product was filtered. Pure Fexofenadine HC1 Form XVI was obtained.*

Please note that a solution containing isopropyl alcohol, hydrochloric acid and fexofenadine free base was obtained in *full dissolution*. And the crystal precipitated out from this solution was *fexofenadine hydrochloride* form XVI. Therefore, the reference demonstrated that that isopropyl alcohol is a solvent that will fully dissolve the compound fexofenadine hydrochloride. The allegation that '163 is not relevant because the solution is free base is misleading and incorrect because a solution containing an acid and a free base forms a salt in situ.

It is common sense that when sugar crystal such as sugar cube is "wet", it lost all crystallinity. Applicants provided **no** factual support that why the wet mass which dissolved the crystal would still contain the claimed limitation of "form X". Further, applicants argued that if the crystalline form converts to amorphous, it is outside the scope of the claims. That is the basis of the rejection since dissolving into isopropanol is the processing step, the product as alleged by applicants is outside the claims, then, without factual evidence, how was the "form X" composition obtained?

3. The rejection of claim 37 under 35 USC 103(a) over MacLaren in view of pharmacopedia or Edgren and Buhler is maintained for reason of record.

The gist of applicants argument is that the rejection was based primarily on the examiner's believe not articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

In the previous office action it was clearly provided references from the analogous art with specific teachings recited explicity. It was evidenced that:

MacLaren et al. '974 disclosed bilayer composition containing a layer of antihistamine fexofenadine in immediate release formulation and a layer of pseudoephedrine in sustain release formulation.

The difference between the instant claims and the prior art is that in the immediate release formulation, the elected active ingredient fexofenadine hydrochloride which would be in its dissolved form (see explaination previously on p.3), cellulose, starch and croscamellose sodium (see col. 12 table 1) and the diluent lactose (col. 11 lines 25-35). Pharmapedia or Ahjel references taught that lactose is the same class of diluents as mannitol. Therefore, it is prima facie obvious to modify the prior art immediate release layer using lactose with mannitol which is a design choice conventionally known to pharmaceutical artist.

The difference between the instant *elected* sustain release layer differ from the prior art in that the instant sustain release layer contains pyrrolidone and vinyl acetate. While the prior art employed alternative sustain release formulation. Pseudoephedrine and pyrrolidone and vinyl acetate sustain release formulation has been conventionally known (see Edgren et al. '712 example 4, pseudoephedrine and pyrrolidon col. 13-14 and generically, the binder is pyrrolidine or optionally mixture of other vinyl monomer including vinyl acetate see col. 6 lines 14-33).

One having ordinary skill in the art in possession of the above references are in possession of the optional choices of diluent or alternative sustain release pseudoephedrine formulation. The picking and choose of an alternative diluent to be prepared into a bilayer system of the prior art with an alternative sustain release layer of conventionally prepared composition, is prima facie obvious, especially, the sustain release formulation is a commercially available formulation (Buhler).

Please note that all references are from the *prior art.* The *suggestion* of alternative diluent is the same "class" of diluents in the pharmaceutical handbooks. The employing of an alternative sustain release material containing pseudoephedrine salt, pyrrolidine and vinyl acetate is that such a sustain release material is *readily commercially available*. Therefore, nowhere in the explanation that examiner's believe played any role.

4. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Feb. 2, 2010

/Celia Chang/
Primary Examiner
Art Unit 1625